

### REQUEUST FOR RECONSIDERATION

The claimed invention has been amended to recite a method of preventing skin damage, which comprises orally administering a composition comprising diacylglyceryl ether represented by the formula (I), as shown above. (See amended claim 1).

The present inventors have found that the claimed method solves the problems of conventional products, such as sunscreens, that have adverse affects on skin after their long-term use. (See present specification at page 2, lines 12-14). In particular, the claimed invention provides a safe and secure method of preventing skin damage due to ultraviolet rays. (See present specification at page 2, lines 15-16). Such a method of preventing skin damage is not described or suggested by the cited references of record. Accordingly, reconsideration of the claimed invention is requested, as further discussed below.

### Rejection under 35 U.S.C. § 103(a)

The rejection of claims 5-10 under 35 U.S.C. § 103(a) as being obvious over JP 07-082162 and Tanaka et al. (U.S. 5,849,309) is traversed and obviated by amendment. The references, alone or in combination, clearly do not describe or suggest the claimed invention, in light of each of the following reasons.

(1) The claimed invention employs a composition containing diacylglyceryl ether represented by the formula (I). (Amended claim 1). In contrast, JP 07-082162 employs a hydrogenation product of a triglyceride of fish liver oil. (See abstract of the reference). In particular, as pointed out in the previous Request for Reconsideration filed January 19, 2006, it is understood that triglycerides have three acyl groups, while diacylglyceryl ethers have two acyl groups and one aliphatic hydrocarbon group. Further, there is no evidence or suggestion that the triglyceride described in the reference should be modified or substituted

with the diacylglyceryl ether of the claimed invention, or that any such modification would be effective.

(2) In the present invention, diacylglyceryl ethers may have unsaturated hydrocarbon groups or acyl groups. For instance, claim 10 recites diacylglyceryl ethers having unsaturated hydrocarbon groups and acyl groups. However, JP 07-082162 employs a hydrogenation product of a triglyceride of fish liver oil. It is understood that the hydrogenation product of a triglyceride only have saturated acyl groups. Thus, the present invention and JP 07-082162 are quite different in terms of the degree of unsaturation.

(3) It is understood that JP 07-082162 is directed to treating a skin damage. In particular, the working example of JP 07-082162 demonstrates that skin damage was treated when first the surface of the skin of guinea pig was damaged with gum tape, and then the hydrogenation product of a triglyceride isolated from a shark liver oil was applied on the damaged surface. However, the claimed invention is directed to preventing a skin damage. As treatment and prevention are understood to be different methods, the disclosure of the reference does not encompass the scope of the presently claimed invention.

(4) The claimed invention is directed to an oral administration. It is noted that the working examples of the present specification demonstrate that a skin damage was successfully prevented when the composition containing diacylglyceryl ether represented by the formula (I) was orally administered. (See, e.g., the Experimental procedure on pages 9-10 of the present specification). However, JP 07-082162 does only describes an external skin preparation (See Claims). As referred to in the above (3), in the working example of JP 07-082162, the hydrogenation product of a triglyceride isolated from a shark liver oil was externally applied on the damaged surface. Thus, the present invention and JP 07-082162 are quite different in terms of the methods of administration.

(5) The Tanaka et al. reference contains no disclosure whatsoever regarding diacylglyceryl ethers. The active compound recited, for instance in claim 1 or 6 of Tanaka et al., is quite different from the diacylglyceryl ether employed in the claimed invention. It is noted that even though Tanaka et al. describes skin activators which are effective for preventing age-related morphological changes in the skin, such disclosure cures the deficiencies of JP 07-082162 or provide motivation for one to achieve the claimed invention.

(6) As discussed above regarding JP 07-082162, the claimed invention is directed to an oral administration. However, Tanaka et al. is directed only to an external skin preparation comprising the active compound recited in claim 1 or 6 of the reference. The method claimed in claims 1-5 of Tanaka et al. comprises administering the active compound *to the skin*. Moreover, all of the formulation examples described in Tanaka et al., such as ointment, are apparently external skin preparations. Thus, the claimed invention and Tanaka et al. are quite different in terms of the methods of administration.

Therefore, in view of the above-stated reasons, the claimed invention is novel and unobvious over JP 07-082162 and Tanaka et al.

Accordingly, withdrawal of the rejection is requested.

#### Rejection under 35 U.S.C. § 112

The rejection of claims 5-10 under 35 U.S.C. § 112, first paragraph, because the present specification does not reasonably provide enablement for a method of *preventing* skin damage, is traversed.

As shown and discussed above, the claimed invention has been amended to specifically recite a “method of preventing skin damage”, which is clearly enabled by the present specification.

Applicants note the Office's position that the working examples described in the present specification are directed "to treating skin damage and not to preventing skin damage." (Present Office Action at page 4, lines 18-19). However, Applicants respectfully submit that the Office has misunderstood and misinterpreted the examples.

In particular, Applicants note that the working examples described in the present specification are directed to *preventing* skin damage, not to treating it. Specifically, in the present specification, Examples 1 and 2 clearly demonstrate that when a composition containing diacylglyceryl ether derived from a shark liver oil had been orally administered to HR-1 hairless mice and guinea pigs for two weeks, and then UVB was irradiated, the formation of wrinkled skin and sagging skin or the formation of skin cancer was successfully prevented.

The specification, as originally filed, also clearly recites in no uncertain terms that the claimed composition is useful in prevention of the skin damage. Accordingly, the Office's attention is directed to following quotations from the present specification:

Based on the test results of Example 1, it was inferred that the feed containing the diacylglyceryl ether-containing composition mixed therein suppressed significantly ( $p < 0.05$ ) wrinkle formation due to UVB irradiation and thus was useful in prevention of the formation of wrinkled skin and sagging skin or the formation of skin cancer. In addition, it was clear that the feed containing the diacylglyceryl ether-containing composition mixed therein suppressed the onset of cancer.

(Page 10, last paragraph of the Example 1).

Based on the test results of experiment 2, it was inferred that because the diacylglyceryl ether-containing composition showed a tendency to suppress UV erythema formation, the composition is useful in alleviation of skin redness (sunburn) or melanism (suntan).

(Page 12, last paragraph of the Example 2).

Thus, Examples 1 and 2 are clearly directed to preventing skin damage, and the present specification well provides enablement for a method of preventing skin damage.

Applicants also note the Office's position that "the inventors have not provided the level of predictability on how and when a person is exposed or infected" and "applicant fails to set forth the criteria that define a method of preventing skin damage". (Present Office Action at page 5, lines 1-10). However, in light of the above, Applicants submit that those skilled in the art who read the working examples could readily understand that a skin damage can be successfully prevented by orally administering the composition, as recited in the claimed invention, before being exposed to a damaging amount of ultraviolet rays. Further, it is noted that other than the working examples, dosing and other factors for orally administering the composition, i.e., criteria, are recited throughout the present specification, e.g., at page 7, lines 21-28.

Accordingly, withdrawal of the rejection is requested.

#### Election of Species Requirement

Applicants wish to thank the Office for acknowledging again that Applicants timely traversed the Election of Species requirement.

It is noted that the genus of claim 5 has been withdrawn. It is also noted that a species of formula (I) was elected in the Response filed September 22, 2005. Further, in response to the Office's comments in the Office Action dated October 19, 2005, Applicants clarified the species and added claim 10, which is commensurate with the elected species and the present specification.

However, in view of the above amendments and remarks, Applicants request that the Examiner withdraw the requirement by indicating that the elected species is allowable, and expand his search of the genus, which should also be indicated as allowable.

Early notification of such allowance is earnestly solicited.

Should the Examiner deem that any further action is necessary to place this application in even better form for allowance, the is encouraged to contact Applicants' undersigned representative at the below listed telephone number.

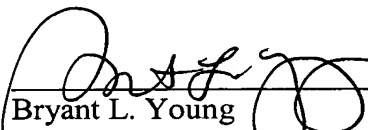
Respectfully submitted,

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